REMARKS

Claims 1-24 are pending in the above-identified application. Claims 11, 13, 15, 17, 19, and 20 have been amended to specify that the prepared form is in the absence of a medicine or solid material prior to enwrapping the medicine or solid material. Support for these amendments can be found throughout the specification and claims as originally filed, for example at col. 4, lines 17-22, as discussed more fully below. Accordingly, no new matter has been entered by way of this amendment.

Reconsideration of the application in view of these amendments and the remarks below is respectfully requested.

Rejection under 35 U.S.C. § 112, first paragraph

The Examiner maintained the rejections of Claims 1-14 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. In particular, it is alleged that the specification fails to provide support for the limitation "packaged in a prepared form **in the absence of medication**" in Claims 1 and 6.

To satisfy the written description requirement, a patent application must describe the invention in sufficient detail that one of skill in the relevant art could conclude that the inventor was in possession of the claimed invention at the time the application was filed. *See Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). There is no *in haec verba* requirement, provided newly added claim limitations are supported in the specification through express, implicit, or inherent disclosure. M.P.E.P. § 2163. The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention now claimed. M.P.E.P. § 2163.02 (citing *Vas-Cath, Inc.* at 1563-64.)

Applicants thank the Examiner for withdrawal of this rejection as it pertains to the limitation "prepared form" as indicated on page 5 of the Office Action. Regarding the limitation "in the absence of medication," Applicants submit that this limitation is also fully supported by the specification, for example, at col. 4, lines 17-22, which recite: "after keeping medicines in a mouth, the swallowing-assistive drink maybe poured into the mouth instead of water and swallowed together with the medicines or after premixing of the medicines with the swallowing-

assistive drink, the obtained mixture (liquid) may be poured into the mouth and swallowed." Thus, the specification clearly sets forth alternate embodiments, one in which the swallowing-assistive drink and medicine are separate, i.e., the swallowing-assistive drink is prepared in the absence of medication, and one in which the swallowing-assistive drink and the medication are mixed together.

Accordingly, Applicants were in possession of the claimed swallowing-assistive drink "packaged in a prepared form in the absence of a medication" at the time the application was filed. Note that the convenience and functionality of a pre-packaged, prepared product in the absence of a medication are important distinctions of the present invention.

In view of the foregoing, Applicants respectfully submit that Claims 1-14 comply with the written description requirement of 35 U.S.C. § 112. Applicants respectfully request withdrawal of this rejection.

Rejection Under 35 U.S.C. § 103

The Examiner maintained the rejection of Claims 1-24 under 35 U.S.C. § 103(a) as being unpatentable over Speck *et al.*, U.S. Patent No. 5,010,061. Specifically, the Examiner asserts that Speck discloses compositions comprising guar flour mixed with a corresponding volume of aqueous liquid and drunk within 0-5 minutes after complete mixing (see col. 3, lines 27-31), and teaches that drugs, vitamins, minerals and all kinds of contrast media can be added to the flour (see col. 3, lines 32-51). The Examiner argues that it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the teachings of Speck *et al.* to devise drinks to help individuals swallowing a medication, and methods for administering a medication, comprising swallowing said drinks. The Examiner states that the expected result would have been a successful drug delivery composition and successful methods for administering drugs. The Examiner also states that the no criticality is seen in the limitation "in a prepared form" and no unusual and/or unexpected results have been shown in the use of a "prepared form" over those disclosed by Speck *et al.* Applicants disagree.

To establish a *prima facie* case of obviousness a three-prong test must be met. First, there must be some suggestion or motivation, either in the references or in the knowledge generally available among those of ordinary skill in the art, to modify the reference. Second, there must be

a reasonable expectation of success found in the prior art. Third, the prior art reference must teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

Applicants submit that Speck *et al.* fails to establish a *prima facie* case of obviousness because the cited reference does not teach all of the limitations of the claimed invention.

Speck *et al.* discloses guar flour formulations for use as a drug or as a food additive. The purpose of that invention is to allow the patient to drink the guar flour itself. The drug and vitamins are ancillary options only, and there is no suggestion that guar flour can make it easier to take medicine. The formulations disclosed in Speck *et al.* are produced without using additive substances to reduce or delay the swelling ability and can be easily consumed in smaller doses and in a more comfortable way than was known in the prior art.

Furthermore, the claims of the instant invention are directed to a swallowing-assistive drink in a prepared form in the absence of a medication and methods for taking medication comprising providing a swallowing-assistive drink in a prepared form in the absence of a medication. Thus, the structural limitation "in a prepared form in the absence of a medication" is a meaningful feature of the claims, and therefore, must be considered in evaluating the patentability of the claims.

Applicants maintain that Speck *et al.* do not teach or suggest a swallowing-assistive drink, much less in a prepared form in the absence of a medication. On the contrary, Speck *et al.* teaches away from guar flour formulations in a prepared form, instead teaching that at room temperature, the formulations remain sufficiently fluid for 5 minutes (col. 3, lines 12-13). The specification of Speck *et al.* repeatedly states that the guar flour formulations disclosed therein must be drunk "rapidly" (col. 4, line 23), "soon after" (col. 4, lines 9-10, 28, and 35), and/or "within 5 minutes" (col. 4, line 17, see also col. 3, lines 30-31 "preferably 0 to 5 minutes after complete mixing"). Contrary to the Examiner's assertion, a person of ordinary skill in the art would not be motivated to package the disclosed guar flour formulations such that the end-user could carry the formulations in a prepared form, nor would there be a reasonable expectation of success in doing so, given that Speck *et al.* discloses repeatedly that the formulations do not remain drinkable for more than 5 minutes after mixing. This teaches directly away from the present invention relating to a prepared form.

The Examiner states that the no criticality is seen in the limitation "in a prepared form" and no unusual and/or unexpected results have been shown in the use of a "prepared form" over

those disclosed by Speck *et al.* Applicants submit that the swallowing-assistive drink of the instant application exhibits unusual and unexpected results over the drink formulations disclosed in Speck *et al.* in that the claimed drink formulations exhibit excellent stability. *See, e.g.*, Specification at col. 2, lines 35-39. In stark contrast to the stability of the prior art formulation, which only allows the prepared formulation to remain drinkable for 5 minutes after mixing, the stability of the claimed formulations allow the swallowing-assistive drink of the instant application to remain sufficiently fluid at room temperature such that the drink can be packaged in a prepared, ready-to-use form. *See id.* Accordingly, the stable formulations of the instant invention allow the end-user to simply open and use the prepared drink.

This advantage over the prior art formulation is substantial from the end-user's point of view because it does not require the end-user to prepare the formulation himself or herself, which can be extremely inconvenient, inconsistent, and messy. In addition, this allows the end-user to carry the packaged drink for use on the go. Furthermore, the stability of the instant drink formulation does not require the end-user to consume the drink within five minutes. The advantage of a stable formulation that can be packaged in a prepared form is also substantial from the manufacturer's point of view, as it allows the manufacturer to control the quality and consistency of the finished product. Moreover, the claimed formulations can be used with any medicine selected by the end-user, unlike those of Speck *et al.* The prior art formulations cannot offer any of these advantages because the prior art formulations do not remain sufficiently stable after mixing to allow packaging in a prepared form, and they are pre-combined with a medicine.

Accordingly, Applicants submit that the PTO has failed to establish a *prima facie* case of obviousness because Speck *et al.* do not teach or suggest a swallowing-assistive drink, much less one that exhibits sufficient stability to allow packaging in a prepared form in the absence of a medication. Nothing in this reference allows the user to solve the problem solved so well by the present invention: a stable, universally-applicable drink formulation in a prepared or pre-packaged form to assist a patient in swallowing his or her medicine, whatever that medicine may be.

Applicants respectfully submit that the cited reference does not render Claims 1-24 obvious because it does not teach or suggest a swallowing-assistive drink in a prepared form in the absence of medication, and thus, does not teach all of the limitations of the claims or provide any of their benefits. Additionally, there would be no motivation to attempt to package the guar

flour formulations disclosed in Speck *et al.* in a prepared form and there would be no reasonable expectation that such modifications could be made, as evidenced by the fact that Speck *et al.* teach that the disclosed formulations only remain drinkable for 5 minutes after mixing. Accordingly, Speck *et al.* cannot support a *prima facie* case of obviousness. Indeed, aside from an incidental and superficial similarity, the two inventions are completely different, and Speck *et al.* in no way address the problem solved by the present invention.

In light of the foregoing, Applicants respectfully submit that Claims 1-24 are not obvious under 35 U.S.C. § 103(a) and hereby request that this rejection be withdrawn.

CONCLUSION

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action have been addressed and that the application is now in condition for allowance. Accordingly, Applicants request the expeditious allowance of the pending claims.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call the undersigned to discuss such issues.

Applicants believe that no fees are due. However, please charge any additional fees that are due, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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